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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0514; FRL-9920-44]

Poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆) - alkyl ethers, disodium salts; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆) alkyl ethers, disodium salts when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops (seed treatment use only) under 40 CFR 180.920 at a concentration not to exceed 0.125% by weight. BASF submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆) alkyl ethers, disodium salts.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with

the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0514, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0514 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0514, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of September 5, 2014 (79 FR 53009) (FRL-9914-98), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10671) by BASF, 26 Davis Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₂) alkyl ethers, disodium salts, polyethoxylation content averages 4-5 moles, Chemical Abstracts Service Registry Number (CAS Reg. No.) 68954-91-6 and poly(oxy-1,2-ethanediyl), α -(3-

carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)- alkyl ethers, disodium salts, polyethoxylation content averages 5 moles (CAS Reg. No. 68815-56-5), when used as an inert ingredient (surfactant) in pesticide formulations applied to growing crops (seed treatment use only) at a concentration not to exceed 0.125% by weight under 40 CFR 180.920. That document referenced a summary of the petition prepared by Exponent on behalf of BASF, the petitioner, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit V.C.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of

FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the

hazards of and to make a determination on aggregate exposure for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts include CAS Reg. No. 68815-56-5, which consists of a C₁₀-C₁₆ linear carbon chain and average polyethoxylation (POE) = 4.5 and CAS Reg. No. 68954-91-6, which consists of a C₁₀-C₁₂ linear alkyl carbon chain and average polyethoxylation (POE) = 5. Although data are not available for CAS Reg. No. 68954-91-6, EPA relied on available subchronic toxicity studies on CAS Reg. No. 68815-56-5. These studies are sufficient to assess the subchronic toxicity of CAS Reg. No. 68954-91-

6 as the only difference between the compounds is the range of carbon chain lengths and the testing of the broader carbon chain length of C₁₀-C₁₆ in CAS Reg. No. 68815-56-5 would include any effects that might be seen in tests of the narrower linear carbon chain length of C₁₀-C₁₂ (in CAS Reg. No. 68954-91-6). Reproduction and developmental toxicity studies were not available for review for either compound, so reproduction data for C12AE6 (CAS Reg. No. 9002-92-0), which is similar to poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts in carbon chain length and average ethoxylation, were used as surrogate data for potential reproductive effects of CAS Reg. Nos. 68815-56-5 and 68954-91-6. Based on analogy to well-known metabolic pathways for other linear alkyl ethers, the major pathway in the primary metabolism of both compounds is expected to be oxidative-reductive ether cleavage. Therefore, the metabolism of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts would result in the formation of the corresponding alkyl alcohol alkoxylate such as C12AE6 (CAS Reg. No. 9002-92-0).

The acute oral and dermal toxicity of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts is low (toxicity category IV). The Lethal Dose (LD)₅₀ is >5,000 milligram/kilogram (mg/kg) in the rat (oral) and rabbit (dermal). They are irritating to the eyes and non-irritating to the skin in rabbits. They are not dermal sensitizers. Acute inhalation toxicity studies were not available.

Subchronic toxicity studies were available in the rat and dog for CAS Reg No. 68815-56-5. CAS Reg No. 68815-56-5 was administered via the diet in both studies. In

a 90-day oral toxicity study in rats, decreased body weight gain was observed at 4% (equivalent to 2,000 mg/kg/day (LOAEL)) of CAS Reg No. 68815-56-5. The NOAEL was 1% (equivalent to 500 mg/kg/day). In a 90-day toxicity study in dogs, toxicity was not observed at 500 mg/kg/day (NOAEL), the highest dose tested.

An acceptable developmental toxicity study is not available; however, in a 2-generation reproduction study in rats on C12AE6, decreased body weight gain was observed in parental animals at 0.5% (equivalent to 250 mg/kg/day). The NOAEL was 0.1% (equivalent to 50 mg/kg/day). Offspring toxicity was manifested as decreased weight gain in pups, increased embryo lethality and soft tissue anomalies at 0.5% (equivalent to 250 mg/kg/day). The NOAEL was 0.1% (equivalent to 50 mg/kg/day). Although fetal qualitative susceptibility is observed in this study, the concern is low because effects occurred only in the presence of maternal toxicity.

Chronic/carcinogenicity studies with poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, alkyl ethers, disodium salts were not available. However, a DEREK structural alert analysis was conducted with poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₂)-alkyl ethers, disodium salt (CAS Reg No. 68954-91-6) and indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, alkyl ethers, disodium salts are not expected to be carcinogenic.

Mutagenicity studies were not available for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts. However, an Ames test is available on CAS Reg. No. 68439-50-9, a surrogate alkyl alcohol alkoxylate. The test was negative.

Neurotoxicity studies were not available for review. Although ataxia was observed in the dams in the developmental toxicity study in rabbits at 100 mg/kg/day, the onset and persistence of ataxia were not reported and thus could not be evaluated. Since evidence of ataxia or other signs of potential neurotoxicity were not observed in the subchronic studies conducted with rats or dogs at doses \geq 500 mg/kg/day, it was concluded that the ataxia observed in the dams was not likely a result of neurotoxicity.

Immunotoxicity studies were not available for review. However, evidence of immunotoxicity was not observed in the submitted studies.

Metabolism studies on poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts were not available for review. However, based on analogy to known metabolic pathways for linear alkyl ethers, the major pathway in the primary metabolism is expected to be oxidative-reductive ether cleavage. Therefore, the primary metabolism of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, alkyl ethers, disodium salts occurs via oxidative-reductive ether hydrolysis resulting in the formation of linear alkyl alcohols and polyethylene glycol metabolites. The alcohols would undergo oxidation by alcohol dehydrogenase and aldehyde dehydrogenase to generate a fatty acid metabolite that is degraded by β -oxidation to carbon dioxide (CO₂) and water (H₂O). The polyethylene glycol metabolites would be degraded via oxidation by alcohol dehydrogenase and aldehyde dehydrogenase to generate a dienoic polyethylene ether acid that may be conjugated and excreted. Also, the alcohol function may be sulfated by sulfotransferases and excreted.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

An acute effect was not found in the database therefore an acute dietary assessment is not necessary. The 2-generation reproduction study in the rat was selected for the chronic exposure for this risk assessment. The NOAEL in this study was 50 mg/kg/day. The LOAEL was 250 mg/kg/day based on decreased weight gain. This study represents the lowest NOAEL in the database in the most sensitive species. The dermal and inhalation absorption rates were assumed to be 100%. The standard inter- and intra-species uncertainty factors were applied. The Food Quality Protection Act

Safety Factor (FQPA SF) of tenfold (10X) was retained for the lack of a developmental toxicity study.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts in food as follows:

Dietary exposure (food and drinking water) to poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts can occur following ingestion of foods with residues from seed-treated crops. Because no adverse effects attributable to a single exposure of poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts were seen in the toxicity databases, an acute dietary risk assessment is not necessary. For the chronic dietary risk assessment, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 3.16, and food consumption information from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). One hundred percent crop treated was assumed, default processing

factors, and tolerance-level residues for all foods and use limitations of not more than 0.125% by weight in pesticide formulations.

2. *Cancer.* A DEREK structural alert analysis indicated no structural alerts for carcinogenicity or mutagenicity. Therefore, poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts are not expected to be carcinogenic and a cancer risk assessment is unnecessary.

3. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

4. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, and tables).

Poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts are not expected to result in residential exposure based on its use pattern as a seed treatment for agricultural crops.

5. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning

the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofpropyl)- ω -hydroxy-, alkyl ethers, disodium salts to share a common mechanism of toxicity with any other substances, and poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofpropyl)- ω -hydroxy-, alkyl ethers, disodium salts does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofpropyl)- ω -hydroxy-, alkyl ethers, disodium salts does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional 10X margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicity database for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofpropyl)- ω -hydroxy-, alkyl ethers, disodium salts

contains two subchronic studies, a reproductive toxicity study, a developmental toxicity study and mutagenicity studies. Qualitative fetal susceptibility was observed in the 2-generation toxicity study in rats. However, concern for fetal effects are low since they only occurred in the presence of maternal toxicity and protecting against maternal toxicity will subsequently prevent fetal toxicity. In addition, the chronic reference dose (cRfD) was based on this study and will be protective of fetal effects. However, since the developmental study in rabbits was unacceptable, the FQPA SF of 10X was retained to account for an incomplete database.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, alkyl ethers, disodium salts from food and

water will utilize 16.2% of the cPAD for non-nursing infants, the population group receiving the greatest exposure. There are no residential uses for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts have no uses that would result in short-term residential exposure, the Agency has determined that it is appropriate to aggregate chronic exposure through food and water only.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Since poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts have no uses that would result in intermediate-term residential exposure, the Agency has determined that it is appropriate to aggregate chronic exposure through food and water only.

5. *Aggregate cancer risk for U.S. population.* Based on a DEREK structural alert analysis and the lack of mutagenicity, poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts are considered not likely to be carcinogenic.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to

infants and children from aggregate exposure to poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

A comment was received from a private citizen who was concerned about the reaction of fatty acid esters to any future chemicals added to the environment. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed because of potential interactions with other chemicals. However, under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute, which EPA has determined here.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfofopropyl)- ω -hydroxy-, (C₁₀-C₁₆)-alkyl ethers, disodium salts (CAS Reg. Nos. 68954-91-6 and 68815-

56-5) when used as inert ingredients (surfactant) in pesticide products used for seed treatment only at a concentration not to exceed 0.125% in the end-use formulation.

VII. Statutory and Executive Order Reviews

This action establishes exemptions to the requirement for a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of

power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 15, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.920, add alphabetically to the table after “Poly(oxy-1,2-ethanediyl), α -isotridecyl- ω -methoxy (CAS Reg. No. 345642-79-7)” the two inert ingredients listed below to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

*	*	*	*	*		
Inert ingredients			Limits		Uses	
*	*	*	*	*	*	*
Poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C ₁₀ -C ₁₂)-alkyl ethers, disodium salts, polyoxylene content averages 4-5 moles (CAS Reg. No. 68815-56-5)			Not to exceed 0.125% for seed treatment use only.		Surfactant	
Poly(oxy-1,2-ethanediyl), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy-, (C ₁₀ -C ₁₆)-alkyl ethers, disodium salts, polyoxyethylene content averages 5 moles (CAS Reg. No. 68954-91-6)			Not to exceed 0.125% for seed treatment use only.		Surfactant	
*	*	*	*	*	*	*